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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,247	10/23/2001	Daniel J. Cook	39726/29361	4051

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POLSTER, LIEDER, WOODRUFF & LUCCHESI, L.C.
C/O AHAI K. AMOS
763 S. NEW BALLAS
ST. LOUIS, MO 63141

EXAMINER
PATEL, MITAL B

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 02/12/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,247

Applicant(s)

COOK, DANIEL J.

Examiner

Mital B. Patel

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-- Th MAILING DATE of this communication app ars on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-16 is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 12/9/03 have been fully considered but they are not persuasive.
2. In response to Applicant's arguments that Waters teaches a wire which is flexible and therefore cannot constitute a rod, the Examiner directs Applicant's attention to Merriam Webster's Collegiate Dictionary, 10th Edition which defines a wire to be "a metal in the form of a usu. Very flexible thread or slender rod." Furthermore, Applicant has established in the history of the prosecution of this application that a rod is solid, and therefore, the Examiner concludes the wire of Waters is a solid rod and maintains the rejection.
3. Please also note that pliability or flexibility does not prevent an element from being solid.
4. In response to Applicant's arguments with respect to "Waters does not describe a device that comprises a connection adapter that is secure to the distal end of a solid, stylet rod," please note that Applicant has not provided in the recitation how the connection adapter is secured to the distal end of the rod, and therefore, the Examiner's rejection with respect to the connection adapter is proper.
5. In response to applicant's argument that McCorkle's stylet wires are too small for an endotracheal tube, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art

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structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, Applicant has not recited dimensions to distinguish that the retainer would support a wide range of endotracheal tubes. Please also note that endotracheal tubes come in a wide range of sizes suited for infants (including premature babies), children, adult, and small animals and some of those sizes may fall within the range of the wire taught by McCorkle.

6. In response to applicant's arguments, the recitation endo-tracheal tube retainer has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

7. In response to applicant's argument with respect to claims 5-9 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

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1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion is found in the knowledge generally available to one of ordinary skill in the art where when of ordinary skill in the art would recognize that the connector of Waters can and may be easily replaced or substituted by another type of connector which is a mechanical expedient without altering the function of the connector. Absent any criticality for specifically using a threaded connector other than for its basic function to connect two elements, one of ordinary skill in the art would logically conclude that any connector may be used in lieu of the threaded connector so long as its basic function is not altered. Therefore, the Examiner maintains that a *prima facie* case of obviousness has been established.

8. Furthermore, in response to Applicant's remarks with respect to a "reasonable expectation of success for the proposed modification," since Applicant has not disclosed a criticality for specifically using a threaded connector one of ordinary skill in the art can conclude that the connector serves the basic function of connecting two elements and therefore, a mechanical expedient of a threaded connector would perform equally as well.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Waters (US 4,388,076).

11. **As to claim 1**, Water teaches an endo-tracheal tube retainer with a solid semi-rigid stylet rod **26** having proximal and distal ends; and a connection adapter **38** tapered from a proximal end of the connection adapter to a distal end of the connection adapter to a distal end of the connection adapter for secure insertion within a range of endotracheal tubes, the adapter being secured to the distal end of the solid stylet rod (See Fig. 1).

12. **As to claim 2**, Waters teaches an endo-tracheal tube retainer wherein the endo-tracheal tube retainer is used to facilitate the removal of the laryngeal mask of the type having a flexible respiratory tube, and that is sufficiently small in diameter to pass through a flexible respiratory tube.

13. **As to claim 3**, Waters teaches a retainer where the stylet is adapted for use independent of the retainer as an intubating stylet.

14. **As to claim 4**, Waters teaches a semi-rigid stylet which is of sufficient length to extend from the laryngeal opening to a point external to a patient's oral cavity.

15. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by McCorkle, Jr. (US 4,582,056).

16. **As to claim 1**, McCorkle teaches an endo-tracheal tube retainer with a solid semi-rigid stylet rod **9A** having proximal and distal ends; and a connection adapter **33** tapered from a proximal end of the connection adapter to a distal end of the connection adapter to a distal end of the connection adapter for secure insertion within a range of

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endotracheal tubes, the adapter being secured to the distal end of the solid stylet rod
(See Figs. 8A-C).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waters (US 4,388,076).

As to claim 5, Waters teaches essentially all of the limitations except for the connection adapter is removably secured to the semi-rigid stylet by means of a threaded connector. It should be noted that Waters teaches a connection adapter that is removably secured to the semi-rigid stylet by a luer lock connection. However, Applicant has not provided a statement as to how the threaded connector is advantages over other types of connectors or provides an unexpected result. One of ordinary skill in the art would have expected the luer lock connector to perform equally as well since the function of the luer lock connector to serve as a connection means is unaltered. Furthermore, it would have been obvious to one of ordinary skill in the art to substitute the luer lock connector with that of a threaded connector as they are mechanical expedients of each other.

19. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCorkle, Jr. (US 4,582,056) in view of Lee (US 5,579,762)

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20. **As to claim 6**, Waters teaches essentially all of the limitations except for wherein an exterior surface of the connection adapter comprises a plurality of longitudinal grooves permitting passage of air and fluids past the endotracheal tube retainer.

However, Lee does teach an adapter with a plurality of longitudinal grooves (See Fig. 3 of Lee) to further facilitate connection to a second element. Therefore, it would have been obvious to one of ordinary skill in the art to modify the connection adapter of Waters to include a plurality of longitudinal grooves to further facilitate connection to a second element.

21. **As to claim 7**, the above combination teaches an endo-tracheal tube retainer wherein the connection adapter is composed of soft, semi-rigid material sufficiently flexible to permit the connection adapter to traverse through the endo-tracheal tube **(See Col. 8, lines 22-24 of Waters)**.

22. **As to claim 8**, the above combination teaches an endo-tracheal tube retainer wherein the longitudinal grooves are equi-spaced around the connection adapter exterior surface.

23. **As to claim 9**, the above combination teaches an endo-tracheal retainer wherein there are at least four longitudinal grooves **(Please note that the Examiner considers the fourth groove to be that between element 88 and 82 of the Lee reference)**.

Allowable Subject Matter

24. Claims 10-16 are allowed over the prior art of record.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

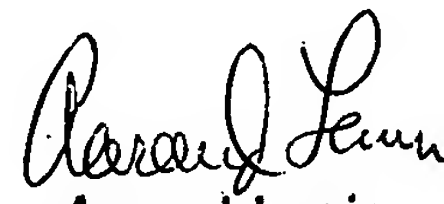
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mbp


Aaron J. Lewis
Primary Examiner